

Remarks

This Amendment is in response to the Office Action dated **December 24, 2008**.

A telephone interview was conducted with the Examiner on 12/16/2008 wherein it was suggested that the title be amended by deleting the term “devices” and replacing it with “balloons”. Amendments were suggested for independent claims 27 and 32. Applicants have amended claim 27 as proposed.

A second telephone interview was conducted with the Examiner on January 27, 2009 wherein amendments to claim 32 were discussed. Applicants have amended claim 32 to further define the at-rest configuration as being when the respective outer and inner surfaces of the article are unstressed. Support is found on the top of page 18 of the specification. No new matter has been added.

Claim Rejections

35 U.S.C. §102(b)

I. Crocker et al.

Claims 27, 28, 32-37 and 65-68

The rejection of claims 27-29, 32-37 and 65-68 under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (6,120,523) has been maintained.

Please note, claim 29 was previously canceled.

Applicants disagree with this rejection.

Applicants maintain that while Crocker et al. do disclose a focalized intraluminal

balloon, Crocker et al. fail to disclose or suggest a balloon comprising, *inter alia*, a lumen extending longitudinally therethrough that passes through tapering proximal and distal wall portions of the balloon.

Applicants maintain that the Crocker et al. balloon has no lumen passing through tapering proximal and distal wall portions. The lumen of Crocker et al. passes through the waist portions as previously argued which are distinct from the tapering wall portions, also referred to in the art as cones.

However, for purposes of expediting prosecution, claim 27 has been amended as suggested by the Examiner in the 12/16/2008 interview.

Claim 27, as amended, now recites, a medical balloon having a longitudinal axis and proximal and distal ends, the balloon formed of a radiation cured polymerizable composition, the balloon connecting to a coaxial shaft at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, and having a central body wall portion between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall portions, respectively, wherein the balloon further comprises a lumen offset from the longitudinal axis, said lumen passing through the tapering proximal and distal wall portions of the balloon.

Crocker et al. fail to disclose or suggest a balloon having a lumen that is offset from its longitudinal axis.

Crocker et al. therefore fail to disclose or suggest all the elements of independent claim 27 as required under 35 U.S.C. §102(b). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir.

1987).

Claim 28 depends from claim 27.

Claim 29 was previously canceled and is no longer pending in the application.

Claim 63 has also been amended to recite that the balloon further comprises a lumen offset from the longitudinal axis, the lumen passing through the tapering proximal and distal wall portions of the balloon, the lumen spaced apart from the coaxial shaft at the proximal end and the coaxial shaft at the distal end.

Applicants also maintain that claim 63, as previously presented, is patentable over Crocker et al. The recitation of the lumen being “spaced apart from the coaxial shaft at the proximal end and the coaxial shaft at the distal end is sufficient to distinguish over the central lumen of the focalized intraluminal Crocker et al. balloon.

However, again for purposes of expediting prosecution, independent claim 63 has been amended in accordance with claim 27.

Claim 64 depends from claim 63 and is not anticipated by Crocker et al. for at least the reasons that claim 63 is not anticipated by Crocker et al.

Claims 32-37

In rejecting claims 32-37, it is asserted in the Office Action that:

Regarding claim 32, Examiner asserts that the first (36) and second balloon (48) layers of Crocker et al. meet the claimed limitations of “having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface.” Examiner asserts that the outer surface of the first layer (36) has a smaller surface area than the inner surface of the second layer (48) because of the stretched areas (near 44 and 40) which are present to accommodate the expansion limiting bands.

Office Action, page 9, second paragraph

Applicants submit that Crocker et al. fail to disclose that the at-rest area of the first layer outer surface is smaller than the at-rest area of the second layer inner surface as recited in claim 32.

It was stated in the Office Action dated 4/17/2008, however, that:

In response to applicants argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "Crocker et al. is silent as to these bands providing stress so as to collapse the article as disclosed in Applicants' specification") are not recited in the rejected claim(s).

Office Action, 4/17/2008, pp. 9-10

For purposes of expediting prosecution, Applicants have amended claim 32 to clarify that the at-rest configuration is when the respective outer and inner surfaces are unstressed.

Claim 32 now recites an article comprising a multi-layer polymeric material film comprising at least first and second layers, each layer having an inner and an outer surface, the first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces. Each of the first and second layers having an at-rest configuration defining an at-rest area on the respective outer and inner surfaces corresponding to the coextensive area, the at-rest area of the first layer outer surface being smaller than the at-rest area of the second layer inner surface, the at-rest configuration being when said respective outer and inner surfaces are unstressed. Support can be found on page 18, top. No new matter has been added.

Crocker et al. is silent as to an article having an at-rest configuration wherein the at-rest area of the first layer outer surface is smaller than the at-rest area of the second layer inner surface when the respective outer and inner surfaces are unstressed.

In Response to Arguments, it is asserted that:

Regarding claim 32, Examiner asserts that the first (36) and second balloon (48) layers of Crocker et al. meet the claimed limitations of "having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface.." Examiner asserts that the outer surface of the first layer (36) has a smaller surface area than the inner surface of the second layer (48) because of the stretched areas (near 44 and 40) which are present to accommodate the expansion limiting bands and that the second layer must cover the first layer.

Final Office Action, pp. 8-9

As previously argued in the Amendment mailed 7/14/2008, Crocker et al. says nothing about stretching any areas near the expansion limiting bands 40, 44 for purposes of accommodating the expansion limiting bands. Crocker et al. disclose that the expansion limiting bands can be applied by coating or mounting on the balloon, but there is no disclosure that there is any stretching or that any other stress applied to the balloon to accommodate the structures. See col. 5, lines 57-65.

The only reference that Crocker et al. make to stretching, is for the purpose of necking down the proximal and distal ends to a diameter which relatively closely fits the portion of the tubular catheter body to which it is to be sealed, or for purposes of obtaining sections of the balloon with a thinner wall portion, in each instance accompanied by a heat set. See col. 6, lines 55-59 and col. 8, lines 59-67.

This has nothing whatsoever to do with providing a first layer outer surface having a smaller at-rest area than a second layer inner surface, the result of which is a section of balloon under stress.

Applicants submit that the amendment to claim 32 reciting that the at-rest configuration is when the respective outer and inner surfaces are unstressed further clarifies this

difference.

As Crocker et al. is silent as to this feature of claim 32, Crocker et al. simply cannot anticipate claim 32.

Claims 33-37 depend from claim 32 and are not anticipated by Crocker et al. for at least the reasons that claim 32 is not anticipated by Crocker et al.

Claims 65-68

Independent claim 65 is directed to a balloon including a balloon body having a proximal end and a distal end, and the balloon comprising circumferential elastic bands at the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

it is asserted in the Office Action that:

Regarding claim 65, Examiner asserts that the bands of Crocker et al. as disclosed as "substantially non-distensible" materials (col 5, ln 20-30), therefore the materials (nylon, polyamide, polyethylene and PET) do have some elasticity and can be considered to fall under the broadest reasonable definition of an "elastic" 1 material (easily resuming original shape after being stretched or expanded; flexible, see elastic. (2007). In The American Heritage® Dictionary of the English Language. Since the materials listed do have expansion recovery and are termed as "expansion limiting bands" they facilitate and undergo some expansion and recovery during balloon inflation and deflation states. Examiner suggests Applicant further clarify the claim with specific elastic characteristics.

Office Action, page 10, 1st full paragraph

This argument, however, is not fully pertinent to claim 65, because a main feature of claim 65 has been left out of the argument, namely, that the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

Thus, Applicants submit that the elasticity of Crocker et al. expansion limiting bands by itself is irrelevant. Rather, the bands must also have a smaller diameter than the balloon

over which they are disposed.

As Crocker et al. teach coating or mounting without any stretching or otherwise putting any stress on the expansion limiting bands, Crocker et al. also does not anticipate this claim.

Crocker et al. disclose that the properties of nondistensibility of the expansion limiting bands is obtained by selecting nondistensible materials or by crosslinking, but not by employing an elastic band having a smaller diameter than the balloon over which it is disposed. See col. 5, lines 33-65. There is absolutely nothing in Crocker et al. to suggest that the expansion limiting bands 40, 44 have a smaller diameter than the underlying balloon layer(s).

Claims 66-68 depend from claim 65 and are not anticipated by Crocker et al. for at least the reasons that claim 65 is not anticipated by Crocker et al.

Applicants respectfully request withdrawal of the rejection of claims 27, 28, 32-37 and 65-68 under 35 U.S.C. § 102(b) as being anticipated by Crocker et al. (6,120,523).

II. Hamlin

Claims 27-28

The rejection of Claims 27-29, 32-35, and 38 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Hamlin (6,132,824).

Applicants maintain their position that Hamlin fails to disclose or suggest a balloon having a lumen that extends through the tapering proximal and distal wall portions.

However, for purposes of expediting prosecution, claim 27 has been amended as discussed above. This amendment is in accordance with the suggestion made by the Examiner during the teleconference of 12/16/2008. Claim 27 now recites that the balloon further comprises

a lumen offset from the longitudinal axis, said lumen passing through the tapering proximal and distal wall portions of the balloon.

Hamlin, like Crocker et al., fail to disclose or suggest a balloon having a lumen that is offset from its longitudinal axis.

Claim 27 as amended is not anticipated by Hamlin.

Claim 28 depends from claim 27 and is not anticipated by Hamlin for at least these reasons.

Withdrawal of the rejection is respectfully requested.

Claims 32-35 and 38

Claim 32 has been amended as discussed above and is now directed to an article having a multi-layer polymeric material film including at least first and second layers, each layer having an inner and an outer surface, the first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, each of the first and second layers having an at-rest configuration defining an at-rest area on the respective outer and inner surfaces corresponding to the coextensive area, the at-rest area of the first layer outer surface being smaller than the at-rest area of the second layer inner surface, the at-rest configuration being when the respective outer and inner surfaces are unstressed.

It is asserted in the Office Action, page 5 that "Hamlin discloses a polymeric balloon that is capable of being radiation cured and is capable of being made of a fluidizable polymer composition, that is comprised of a multi-layer polymeric film (64, 66, 68) wherein a first (64, 66) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 5-6)."

Again, Hamlin fails to disclose or suggest an at-rest area of the first layer outer surface being smaller than the at-rest area of a second layer inner surface wherein the at-rest areas are coextensive.

While Figs. 5 and 6 and the corresponding description discuss multilayers, there is absolutely no disclosure as to an at-rest area of a first layer outer surface being smaller than an at rest area of a coextensive second layer inner surface, the result of which is an area of the balloon that is under stress. Hamlin discuss the conventional coating and coextruding, but nothing more.

Furthermore, Applicants see no specific disclosure in Hamlin as to the at-rest and open configurations that result in a change in surface area referred to in the Office Action, and even if there was such a reference, such a feature is not the same as that recited in independent claim 32 wherein an first layer outer surface has a smaller area than a second layer inner surface so as to result in an interface that is under stress in the at-rest configuration of the balloon.

As discussed above, while there is no recitation of the "stress" in the claims, this is an inherent result of having a smaller first layer outer surface area that is coextensive with an underlying second layer inner surface area.

Therefore, claim 32 cannot be anticipated by Hamlin because this feature is not disclosed by Hamlin.

Claims 33-35 and 38 depend from claim 32 and are not anticipated by Hamlin for at least the reasons that claim 32 is not anticipated by Hamlin.

Applicants respectfully request withdrawal of the rejection of claims 27-29, 32-35, and 38 under 35 U.S.C. § 102(b) as being anticipated by Hamlin (6,132,824).

III. Boussignac et al.

The rejection of Claims 63-64 under 35 U.S.C. § 102(b) as being anticipated by Boussignac et al, (5,000,734) has been maintained.

Applicants disagree.

As previously discussed, claim 63 is directed to an embodiment wherein the medical balloon is formed from a radiation cured polymerizable composition. Other features are recited.

Applicants have amended claim 63 to clarify that the composition is “polymerized” rather than “polymerizable”.

Boussignac et al. fail to disclose any specific polymer material whatsoever, much less forming balloons from radiation cured, polymerized polymer materials as recited in claim 63, nor could Boussignac et al. be found to inherently disclose such materials.

Claim 63 simply cannot be anticipated by Boussignac et al. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

It is now asserted in the Final Office Action, Response to Arguments that:

Regarding claim 63, Examiner asserts that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) Also when the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed Cir 1983) Therefore the balloons of Anderson (3) and Boussignac et al.. (5) are composed of several different materials of which polyethylene is disclosed, Examiner considers the radiation curing of polyethylene to result in an indistinguishable product from a polyethylene product

formed via a different means of curing (such as heat). If Applicant wishes to gain patentability of this process Applicant must direct method/process claims towards this specific claim scope.

Final Office Action, pp. 9-10

This is simply incorrect and the analysis thus flawed.

Radiation cured polyethylene results in a crosslinked polyethylene, very much distinguishable from thermoplastic polyethylene and the resultant product made therefrom would be readily distinguishable. With the radiation cured or crosslinked polymer, bonds will be seen between polymer chains whereas with thermoplastic polyethylene no bonds will exist between the polymer chains, and the resultant physical properties of crosslinked versus noncrosslinked polyethylene will also be different.

Boussignac et al. is silent as to radiation curing, i.e. crosslinking, any material, and fail to disclose or suggest that an expandable medical may be formed using such a material.

Claim 64 depends from claim 63 and is not anticipated by Boussignac et al. for at least the reasons that claim 63 is not anticipated.

Withdrawal of the rejection is respectfully requested.

IV. White, Jr.

Claim 65

The rejection of claim 65 under 35 U.S.C. § 102(b) as being anticipated by White, Jr. (4,327,734) has been maintained.

Claim 65 has been rejected under 35 U.S.C. § 102(b) as being anticipated by White, Jr. (4,327,734).

Applicants traverse the rejection.

It is asserted in the Office Action that:

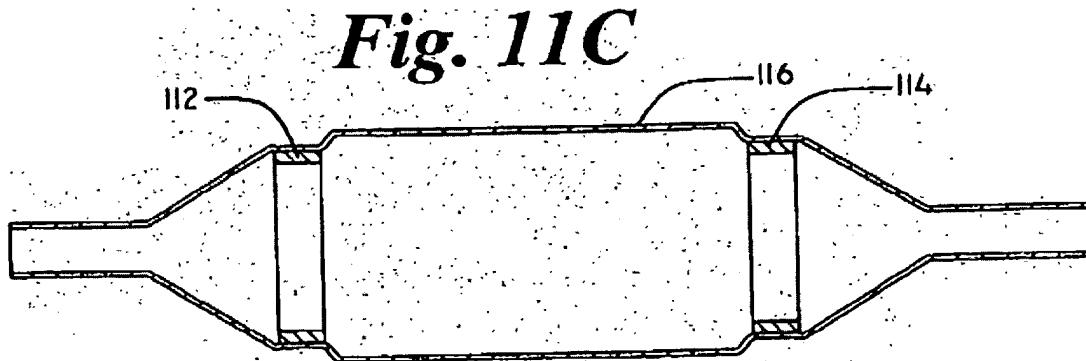
Regarding claim 65, White, Jr. discloses a balloon (20) comprising a balloon body (38) having a proximal and distal end, and the balloon comprising circumferential elastic bands (46) at the proximal end or distal end of the balloon body, the elastic bands (46) in their rest configuration have a smaller diameter than the balloon body in its rest configuration (Figure 1) verses the inflated configuration (Figures 2-3) (Figures 1-3).

Office Action, page 6

Applicants disagree.

Claim 65 is directed to and embodiment of a balloon including a balloon body having a proximal end and a distal end, and the balloon comprising circumferential elastic bands at on the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

Fig. 11C has been reproduced below to illustrate the elastic bands 112, 114 located on the proximal end and distal end of the balloon body:



Applicants submit that White, Jr. discloses a balloon catheter assembly including:

... a hollow cannula 22 One end of cannula 22 is adapted to be connected to a source of fluid in a conventional manner. Mounted in the other end of cannula 22 is an enlarged end 24 of a pin 26. The smaller end of the pin 30 is positioned within a self-sealing plug 34 mounted in the open end portion 36 of an expandable balloon 38 ... Surrounding the portion of the balloon where the plug 34 is located on the exterior surface thereof is an elastic band 46 of plastic or rubber material which assists in retaining the pin in the self-sealing plug and is utilized to assist

with the self-sealing plug in sealing the open end of the balloon when the cannula and pin combination is removed therefrom during detachment.

Col. 3, lines 12-46

The elastic band 46 disclosed by White, Jr. is not located on the balloon body whatsoever. The location of the elastic bands 112, 114 in the present application is important because the bands have a smaller diameter than the underlying balloon, and are stretched from their at-rest diameter to reach their diameter on a form. When the form has been removed, the composite balloon is stressed by the bands 112, 114 to collapse to their rest position. This aids in obtaining a small deflated profile. See page 17, lines 32-33 to page 18, lines 1-11.

As the elastic band 46 disclosed by White, Jr. is not located on the balloon body, it cannot anticipate claim 65. See Figs. 1-3 of White, Jr. below for elastic band 46:

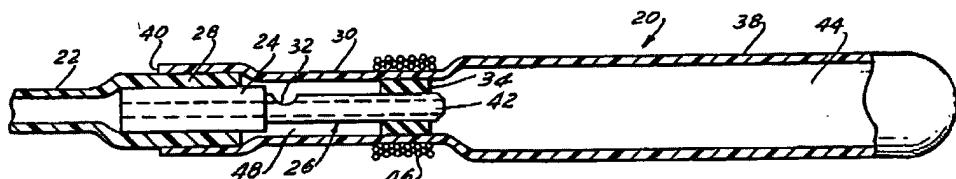


FIG. 1

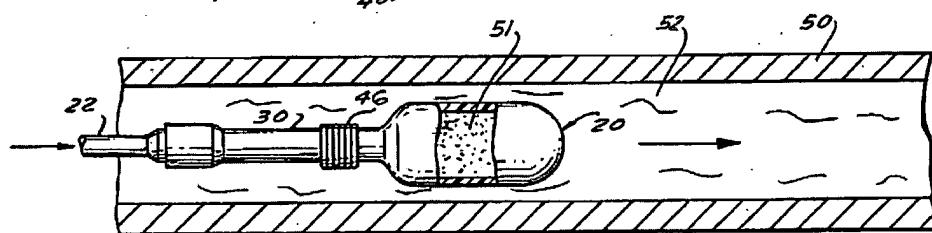


FIG. 2

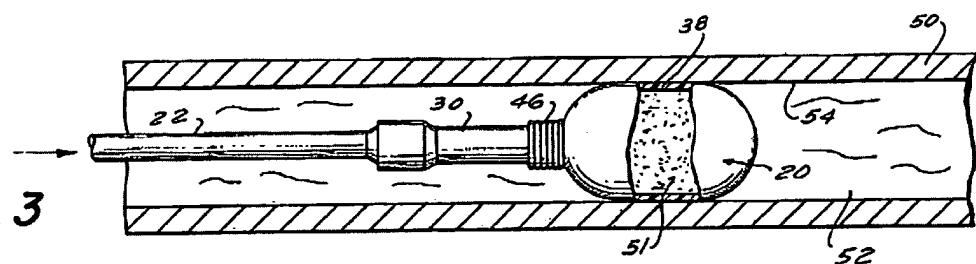


FIG. 3

Thus, not all of the elements of claim 65 are disclosed by White, Jr. as required by

35 U.S.C. §102(b). Id. at 1053.

Applicant respectfully requests withdrawal of the rejection of claim 65 under 35 U.S.C. §102(b) as being anticipated by White, Jr. (4,327,734).

V. Anderson

Claims 63-64

The rejection of claims 63-64 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson (6,007,517) has been maintained.

As previously discussed, claim 63 is directed to an embodiment wherein the medical balloon is formed from a radiation cured polymerizable composition. Other features are recited.

Applicants have amended claim 63 to clarify that the composition is “polymerized” rather than “polymerizable”.

Anderson is silent as to forming a balloon from any polymer material that is cured, polymerized, or otherwise reacted, much less balloons specifically formed of a radiation cured polymer, nor is radiation polymerization an inherent polymer trait and is certainly not inherent in balloon materials. Again, it was asserted in the Final Office Action, Response to Arguments that:

It is now asserted in the Final Office Action, Response to Arguments that:

Regarding claim 63, Examiner asserts that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) Also when the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed Cir 1983) Therefore the balloons of Anderson (3) and Boussignac et al. (5) are composed of several different materials

of which polyethylene is disclosed, Examiner considers the radiation curing of polyethylene to result in an indistinguishable product from a polyethylene product formed via a different means of curing (such as heat). If Applicant wishes to gain patentability of this process Applicant must direct method/process claims towards this specific claim scope.

Final Office Action, pp. 9-10

This is simply incorrect and the analysis thus flawed.

As discussed above, crosslinked polymers are readily distinguished from non-crosslinked polymer materials due to the fact that bonds exist between polymer chains in a crosslinked polymer material.

Anderson are clearly not disclosing crosslinked materials. In fact, Anderson state that “[s]uitable materials for any scaffolding include high or low density polyethylene (or other standard balloon material) or any other similar material.” Col. 9, lines 44-46.

One of skill in the art would not understand the standard balloon materials disclosed by Anderson to be radiation cured.

Claim 63 simply cannot be anticipated by Anderson. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 64 depends from claim 63 and is not anticipated by Anderson for at least the reasons that claim 63 is not anticipated.

Withdrawal of the rejection is respectfully requested.

35 U.S.C. §103(a)

I. Crocker et al.

Claims 30-31

The rejection of claims 30-3 1 under 35 U.S.C. §103(a) as being obvious over Crocker et al. has been maintained. It is asserted in the Office Action that:

Crocker et al meets the claim limitations as described above except for the specific embodiment being used in with a stent or with a rapid exchange catheter Crocker et al.. teaches a specific medical balloon structure that is disclosed of being used with rapid exchange and for delivery of stents to the vascular system (col 3, In 40-70, col 4, In 40-70, see summary of invention) ... it would have been obvious to use the medical balloon as disclosed by the **various embodiments and the** disclosure of Crocker et al. in order to achieve a versatile controllable balloon element.

Office Action, pp 7-8

Claims 30-31 depend from claim 27.

As discussed above, claim 27 has been amended to recite that the balloon further includes a lumen offset from the longitudinal axis that passes through the tapering proximal and distal wall portions of the balloon.

Crocker et al. fail to disclose or suggest a medical balloon having a lumen offset from the longitudinal axis that passes through the tapering proximal and distal wall portions of the balloon.

Claim 27 as amended is not obvious over Crocker et al.

Claims 30-31 are not obvious over Crocker et al. for at least the reasons that claim 27 is not obvious over Crocker et al.

Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Claims 27, 28, 30-38 and 63-70 are pending in the application. Applicant has addressed each of the issues presented in the Office Action. Based on the foregoing, Applicant respectfully requests reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 19, 2009

By: /Lisa Ryan-Lindquist/
Lisa R. Lindquist
Registration No.: 43071

6640 Shady Oak Dr., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

f:\wpwork\lr\10856us01_amd_20090112.doc